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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/263,626

03/05/1999

PAUL A. MOORE

PF466

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22195

7590

06/10/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/263,626	Applicant(s) MOORE ET AL.	
	Examiner Michael Brannock	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 156-191 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 156-169 and 172-191 is/are allowed.
- 6) ☐ Claim(s) 170, 171 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 4/13/04, have been entered in full.

Response to Amendment:

Applicant is notified that any remaining rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claims 170 and 171 are rejected 35 U.S.C. § 112 first paragraph, as set forth previously. Specifically, because the claims are not enabled in their full scope, i.e. the specification, while being enabling for a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and for polypeptides consisting of fragments of SEQ ID NO: 2 useful for the production of antibodies specific to SEQ ID NO: 2, and for polynucleotides that specifically hybridize to a polynucleotide of SEQ ID NO: 1, does not provide enablement for polynucleotides that are not useful for raising specific antibodies or for specific hybridization.

As set forth previously, assuming that one skilled in the art would understand that the instant receptor is expressed in activated T-cells as opposed to resting T-cells, then it is reasonable to also assume that one of skill in the art could use polynucleotides of SEQ ID NO: 1 as hybridization probes to detect activation of T-cells. Similarly, it is reasonable to assume that the skilled artisan could use the polypeptides of SEQ ID NO: 2 to raise antibodies useful for the detection and/or isolation of activated T-cells. However, the claims encompass a virtually limitless number of polynucleotide variants of SEQ ID NO: 1. It is reasonable to assume that

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many of the encompassed polynucleotides could be used as hybridization probes that are specific to SEQ ID NO: 1 such that detection of activated T-cells could be achieved, yet the claims are not so limited to hybridization probes and the specification has failed to teach how to use other claimed polynucleotides that could not be used as probes for SEQ ID NO: 1. Of those polynucleotides that may not be useful as probes, it can be expected that only a small number will encode a polypeptide of SEQ ID NO: 2 due to the degeneracy of the genetic code. This small number is enabled. However, polynucleotides encoding variants of SEQ ID NO: 2 are not enabled, as set forth previously, particularly at page 6 of Paper 6 (1/3/00) and on page 8 of Paper 11 (8/29/02).

Applicant argues that the claims have been added are directed to polynucleotides that hybridize to SEQ ID NO: 1. This argument has been fully considered but not deemed persuasive. As set forth above, the claims are not limited to polynucleotides that can be used as taught in the specification, e.g. to encode polypeptides capable of producing antibodies that specifically detect activation of T-cells or as specific hybridization probes that detect activation of T-cells. The skilled artisan would understand that the claims encompass a substantial subgenera that could not be used as such, e.g. they may not encode antibodies that are specific or they may hybridize to other polynucleotides and not provide a true detection of activated T-cells.

Claims 170 and 171 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth previously in item 11 of Paper 15.

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The specification discloses a polynucleotide of SEQ ID NO: 1, yet the claims encompass polynucleotides not described in the specification, e.g., sequences from other species, mutated sequences, allelic variants, or sequences that have a recited degree of identity or that merely hybridize to SEQ ID NO: 1. Although one of skill in the art would reasonably predict that these sequences exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

As set forth previously, simply writing down or verbalizing that an unknown polynucleotide should hybridize to SEQ ID NO: 1 under a recited set of conditions in no way puts one in possession of such a polynucleotide and nor does this recitation provide any particular information as to the polynucleotide sequence. With the exception of the of the polynucleotide of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants that need only hybridize to SEQ ID NO: 1.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX Months. Any inquiry

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concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER

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June 8, 2004